



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,108	04/05/2001	Stephen K. Sundquist	P-9327.00	5008
27581	7590	01/08/2004	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			BOCKELMAN, MARK	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 01/08/2004

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/827,108

Applicant(s)

SUNDQUIST ET AL.

Examiner

Mark W Bockelman

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 2, 11, 13, 15, 19, 20, 24, 26, 28, 29 and 32-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-10, 12, 14, 16-18, 21-23, 25, 27 and 30-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 5-10, 12, 14, 16-17, 21-23, 25, 27, 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonner et al USPN 5,902,331.

Bonner et al USPN 5,902,331 show (e.g. fig 6) an elongate guiding device 150 with a distal end 154 having an expandable balloon 152 which is (capable of acting as an expandable fixation member as applicant's balloon), a coupling member 70 and electrode assembly 12 with tines as a fixation means (or helix –fig 7). The coupling member may be fastened to the guiding device to form a unified member. The coupling member is considered to be a rail, in the broadest meaning of the word permitted by Webster's dictionary. Similarly, the coupling member may also be fastened and unfastened to the electrode assembly and can thus slidably engage the electrode assembly and prevent lateral movement while coupled. The couple assembly can itself be considered to be a rail having a rail extension 62 flexible enough to open to receive the catheters which, when held properly keeps the electrode assembly from twisting

(about the guide) during slidable engagement (i.e. upon retraction –column 15 lines 30-40). The examiner notes that the guiding catheter has a guidewire lumen extending there through (column 15 lines 62-67) which is capable of delivering fluids (claim 8-10) and the balloon lumen “included” in the coupling member since it passes through the coupling member lumen 68. The port at 154 is proximal (i.e. proximate) the balloon member.

Claims 1, 3, 5-10, 12, 14, 16-17, 21-23, 25, 27, 30-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Landberg et al USPN 6,527,769.

Landberg et al show on the front cover, a guiding member 380, with a balloon 384 and a port 338 or 378 capable of delivering fluids. A coupling member 312 in the form of a rail slidably engages an electrode assembly 314, which has a fixation member 386 thereon.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by VandenEinde et al USPN 5,415,639.

VandenEinde et al show a balloon catheter guide member with a coupler 314 (and or 302) for slidably engaging a guidewire. Applicant’s recited intended use of the device with an electrode assembly fails to distinguish over VandenEinde since VandenEinde could potentially use an electrode assembly guidewire as that described in Hofmann et al USPN 5,704,908.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 and 18 are rejected under 35 U.S.C. 102(b or e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over or Bonner et al USPN 5,902,331. While applicant recites rails such as H-rail and K-rail, it is unclear if this intended to be the shape of the rail or not. In this regard, the Bonner rail is considered to be each of these types of rails, or otherwise the double clamp forms a general h-shape rail. Alternatively, to shape the rail member of Bonner in any shaped desired that still form the function of joining the electrode assembly to the balloon containing guide member would have been obvious design choice.

Response to Arguments

Applicant's arguments filed 11-03-03 have been fully considered but they are not persuasive. Rather than point out any structural differences between the claimed invention and the references applied by the examiner the applicant appears to have taken the position that the claimed intended use of a balloon member provides a structural distinction over the balloon members described in each of the applied references. These balloon members all appear to be fully capable of performing a

fixation function. Applicant has provided no disclosure or arguments to establish the contrary.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number is (703)-308-2112. The examiner can normally be reached on Monday - Thursday 10-8:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Application/Control Number: 09/827,108

Page 6

Art Unit: 3762

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.

MWB

January 7, 2004

Mark Docketman
MARK DOCKETMAN
PROPERTY ENGINEER